

**REMARKS**

The above amendments are submitted in response to the Office Action of July 8, 1997 and in accordance with suggestions made by Examiner Shay during an telephonic interview held on December 9, 1997. Reconsideration and allowance are requested.

The present invention is directed to laser surgical systems employing a particular class of lasers operating in the mid-infrared region (approximately 2 micrometers). These laser sources are generally known as "rare earth lasers." The present invention is based upon the discovery that such *rare earth lasers* can be coupled to *low hydroxyl ion content silica fibers* to deliver radiation to a surgical site.

More specifically, the invention is based, in part, on the discovery that the wavelengths of infrared radiation emitted by rare earth lasers are particularly suited for surgery because such *wavelengths in the range of 1.4 to 2.2 millimeters* are strongly absorbed in biological tissue. The invention is also based on the discovery that low hydroxyl ion content silica fibers have both the flexibility and the high transmissivity that enables the transmission of such wavelengths to remote surgical sites to facilitate removal or repair of biological tissue. When operates in a pulsed mode the systems of the present invention can deliver sufficient energy to remove tissue and when operated in a low power, continuous wave mode, biological tissue repair can be achieved.

During the interview on December 9, 1997, applicant agreed to submit three Terminal Disclaimers to overcome the judicial-doctrine, double-patenting rejections set forth on pages 3 and 4 of the Office Action. These Disclaimers are submitted herewith and entry of the disclaimers is requested.

The only other ground for rejection was based on obviousness grounds. On page 2 of the Office Action, the claims were rejected under 35 USC 103 as obvious over Peyman in view of Eisenberg and "judicial notice." During the telephonic interview, it was noted that both references were directed to laser surgical instruments involving



minimal (or no) transmission of laser energy through optical waveguides. Contrary to the statement in the Office Action that it was known to employ low hydroxyl ion content silica fibers to transmit the desired wavelength, Applicant submits that these references demonstrate that the solution to problem of transmitting mid-infrared radiation over a distance was not known.

The Peyman et al. '866 patent discloses an ophthalmic laser surgical method for treating the anterior portions of an eye while avoiding damage to the fundus and retina. To accomplish this, Peyman et al. "aim" or focus radiation onto the cornea, lens or extracapsular membranes. All of Peyman's experiments and examples employ mid-infrared radiation (e.g., from a Nd:YAG laser) which is *transmitted directly (i.e. through air)* to the eye.

The Eisenberg '942 reference similarly discloses infrared laser devices for ophthalmic use (e.g. phakoemulsification, a process in which the lens of the eye is fragmented and removed prior to the implantation of plastic replacement). Eisenberg's device is a "laser handpiece" having a pencil-shaped laser coupled to a very short distal probe. Like Peyman et al., Eisenberg's preferred construction is a *free air transmission* device. A hollow probe (element 20, FIG. 1) coupled to an air source serves to transmit the radiation from the laser to the lens. This hollow probe is a needle approximately 2.5 cm long (see, Eisenberg's specification at column 4, lines 10-32) which is positioned in contact with target tissue within the eye and then filled with air.

Although both Peyman et al. and Eisenberg suggest that optical fibers can be employed with their devices, neither reference demonstrates any appreciation of the problem of high losses in conventional silica fibers in the desired wavelength range. Since neither reference was concerned with the transmission of radiation to a remote surgical site (e.g. one or more meters away), the cited references did not even mention the problem that conventional silica-based fibers even though flexible enough to be used, had unacceptably high losses. Since neither reference appreciated the problem, neither reference provides any suggestion as to a solution.

During the interview, Applicant proposed to address the issue of the state of the art with respect to mid-infrared transmissivity in optical fibers by submitting a declaration. Accordingly, the Declaration of Dr. Sinofsky is submitted herewith. This declaration refutes the position taken in the Office Action (that it was known to employ low hydroxyl ion content silica fibers to transmit the desired wavelength). As noted by Dr. Sinofsky in the accompanying Declaration:

To achieve a practical laser surgical system, however, I also had to improve upon the transmission characteristics of silica fibers. At first, I was unable to locate any existing glass fibers that could transmit the required energy levels for the required distance, which was on the order of ten feet. Following further experimentation and research, I discovered that the attenuation of laser radiation in this wavelength range was greatly affected by the presence of hydroxyl ions in the glass fibers, and, ultimately, discovered that silica fibers with reduced hydroxyl ion contents were capable of delivering the desired energy levels for the required distances to achieve his laser surgical system....The low hydroxyl ion content fibers which I used were not commercially available but rather were special ordered. The manufacturer sold these products to me without any guarantee that they would be successful in transmitting radiation in the specified IR wavelength range. (Sinofsky Declaration, paragraphs 10 and 11).

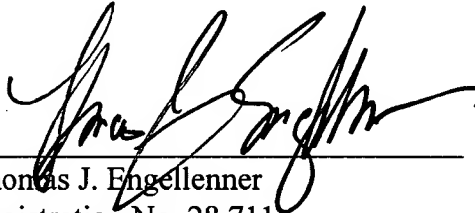
In addition, the above amendment is submitted to clarify applicant's contribution to the art. Claim 60 (the only independent claim) has been amended to now recite a *flexible, elongate* optic fiber is employed and that the fiber is a silica fiber having a low hydroxyl ion content to reduce absorption of said laser energy during transmission through said fiber. Neither reference discloses the use of a flexible, elongate optical fiber and neither suggests the use of low hydroxyl ion content silica as the fiber material. No new matter has been added. Support for the amendments can be found, inter alia, at page 1, lines 13-23; page 3, lines 1-5 and in the drawings.

Thus, for all the reasons above, it is believed that the presently pending claims are patentably distinct from the prior art references and early reconsideration and passage to allowance are requested.

Respectfully submitted,

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